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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,997	12/15/2003	Jon E. Ness	10181.210-US	6691

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EXAMINER	
MOORE, WILLIAM W	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/736,997	NESS ET AL.	
	Examiner	Art Unit	
	William W. Moore	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *110-123* is/are pending in the application.

4a) Of the above claim(s) *121-123* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *110-115 and 120* is/are rejected.

7)☒ Claim(s) *116-119* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20040322*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

1-129. Claims 110-120, each drawn in part to an isolated individual protease that comprises a different catalytic domain sharing at least 70% sequence identity with a catalytic domain amino acid sequence set forth in, consecutively, SEQ IDs NOs:131-136 and 138-260 and a composition comprising each and a detergent, classified in, *inter alia*, class 435, subclass 219.

130-259. Claims 121-123, each drawn in part to an isolated nucleic acid sequence encoding individual protease that comprises a different catalytic domain sharing at least 70% sequence identity with a catalytic domain amino acid sequence set forth in, consecutively, SEQ IDs NOs:131-136 and 138-260, and to vectors and host cells comprising each and a recombinant method of making each utilizing said vectors and/or host cells, classified in, *inter alia*, class 536, subclass 23.2.

Inventions of Groups 1-129 are unrelated, respectively, to inventions of Groups 130-259. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups 1-129 are independent chemical entities distinct from the inventions of Groups 130-259 and require separate searches in the patent and non-patent literature.

Inventions of Groups 1-129 are unrelated, one to another, because each comprises a genus of proteases wherein each residual protease is a distinct product having a unique primary structure. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be used together and require separate searches in the patent and non-patent literature.

Inventions of Groups 130-259 are unrelated, one to another, because each comprises distinct polynucleotides encoding distinct protease products having a unique primary structure. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant

case the different inventions are not disclosed to be used together and require separate searches in the patent and non-patent literature.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Elias Lambiris on 7 July 2005 a provisional election was made with traverse to prosecute the invention of Group 4, an isolated protease comprising a catalytic domain sharing at least 70% sequence identity with a catalytic domain amino acid sequence set forth in SEQ ID NO:134, and compositions comprising the protease. Affirmation of this election must be made by applicant in replying to this Office action.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

Acknowledgment is made of applicant's claim to priority of the 3 April 2000 filing date of the US provisional application serial No. 60/194,143 the disclosure of which is shared by the instant application.

Information Disclosure Statement

Applicant's Information Disclosure Statement filed 22 March 2004 is herby acknowledged

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 110-113 and 120 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Although the specification discloses twenty-six species of protease catalytic domains that diverge no more than 5% from the elected catalytic domain amino acid sequence set forth in SEQ ID NO:134, which population of species is considered adequate to establish possession of this limited genus, the specification fails to exemplify or describe the preparation of the subject matters of the divergent proteases of claims 110-113 that diverge by more than 5%, to as much as 30%, from the elected catalytic domain amino acid sequence set forth in SEQ ID NO:134. Neither the claims nor the specification describe where the differences occur nor what the differences might be and the specification does not otherwise disclose or suggest the nature or source of any of the generic proteins that meet the limitations of the claims. "While one does not need to have carried out one's invention before filing a patent application, one does need to be able to describe that invention with particularity" to satisfy the description requirement of the first paragraph of 35 U.S.C. § 112. *Fiers v. Revel v. Sugano*, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993). The specification furnishes no relevant identifying characteristics of a genus of proteases that diverges at more than 5% of the positions of the sequence set forth in SEQ ID NO:134, nor does it provide any characteristic permitting a correlation between undisclosed structures of more divergent protease domains and disclosed amino acid sequences of SEQ ID NO:134.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 110-115 and 120 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 20-23 of the commonly-assigned U.S. Patent No. 6,777,218. Although the conflicting claims are not identical, they are not patentably distinct from each other because the catalytic domains of the subtilases, and detergent compositions comprising, same of claims 110-115 and 120 herein share at least 96% identity with the catalytic domains, and detergent compositions comprising same, of the patented claims 1-7 and 20-23.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. § 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. § 122(b). Therefore, this application is examined under 35 U.S.C. § 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

Claims 110 and 111 are rejected under 35 U.S.C. § 102(b) as being anticipated by van der Laan et al., 1991, made of record herewith, who disclose the amino acid sequence of a protease isolated from *Bacillus lentus*, the subtilisin 309, the catalytic domain of which shares 84% sequence identity with the elected catalytic domain sequence set forth in SEQ ID NO:134.

Claims 110-112 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kobayashi et al., 1995, made of record herewith, who disclose the amino acid sequence of a protease isolated from the *Bacillus* species KSM-16, the catalytic domain of which shares 85% sequence identity with the elected catalytic domain sequence set forth in SEQ ID NO:134.

Claims 110-112 and 120 are rejected under 35 U.S.C. § 102(e) as being anticipated by Christianson et al., US 5,340,735, made of record with Applicant's Information Disclosure Statement, who disclose the amino acid sequence *Bacillus lentus* subtilisin PB92 protease, the catalytic domain of which shares 85% sequence identity with the elected catalytic domain sequence set forth in SEQ ID NO:134, and a detergent composition comprising same.

Claims 110-115 and 120 are rejected under 35 U.S.C. § 102(e) as being anticipated by Mikkelson et al., US 6,777,218, who disclose the amino acid sequence of a *Bacillus* subtilisin having the amino acid sequence set forth in their SEQ ID NO:2, the catalytic domain of which shares 96% sequence identity with the elected catalytic domain sequence set forth in SEQ ID NO:134, and a detergent composition comprising same.

Conclusion

Claims 116-119 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Not prior art to an invention claimed herein, the publication of Weber et al. is made of record herewith as pertinent to Applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Ms. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore
22 August 2005

KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER